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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,198	01/20/2000	Shigeaki Kato	06501-054001	5541

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EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 01/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/489,198

Applicant(s)

KATO ET AL.

Examiner

Joseph F Murphy

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**– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 October 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 12-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Formal Matters***

Claims 8-11 were amended in Paper No. 19, 10/23/2002. Claims 1-27 are pending. Claims 1-7, 12-27 stand withdrawn from consideration pursuant to 37 CFR 1.142(b). Claims 8-11 are under consideration.

***Response to Amendment***

Applicant's arguments filed 10/23/2002 have been fully considered but they are persuasive in part.

The rejection of claims 8-11 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps wherein the omitted steps are: the converted ligand molecule, after conversion to the active form, binds to and activates the nuclear receptor, has been obviated by Applicant's amendment, and is thus withdrawn.

The rejection of claims 8-11 under 35 U.S.C. 112, second paragraph for recitation of the term ligand precursor has been withdrawn.

The rejection of claims 9 and 11 under 35 U.S.C. 102(a) as being anticipated by Zhao et al. (1997), has been withdrawn.

***Claim Rejections - 35 USC § 112 second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-11 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8-11 are rejected under 35 U.S.C. 112, second paragraph as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: that the test gene comprises a sequence which encodes a protein which is to be tested for activity which converts the inactive ligand into the active form, as well as comprising sequences encoding the nuclear receptor, the response element, and the reporter gene. As currently written, the claims set forth that the test need only comprise sequences encoding the nuclear receptor, the response element, and the reporter gene

***Claim Rejections - 35 USC § 102***

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8 and 9 stand rejected under 35 U.S.C. 102(b) as being anticipated by WO 9621677 (Moore et al.).

WO 9621677 discloses methods of determining whether a test protein is capable of interacting with a nuclear hormone receptor, the RXR receptor. WO 9621677 at 2. Further disclosed are methods where the host cell is further treated with a ligand, and identifying a ligand-dependent interacting protein by its ability to increase expression of a reporter gene in

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both the presence and absence of ligand treatment. *Id.* at 3. This meets the limitations of the indicated claims, because the method taught by WO 9621677 involves transfection of a test gene into a cell, treating a cell with ligand, and isolating the positive clones. *Id.* at 12. Thus the limitations of claims 8 and 9 are anticipated.

No arguments were addressed to rebut this rejection.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over WO 9621677 (Moore et al.).

WO 9621677 discloses methods of determining whether a test protein is capable of interacting with a nuclear hormone receptor, the RXR receptor. WO 9621677 at 2. Further disclosed are methods where the host cell is further treated with a ligand, and identifying a ligand-dependent interacting protein by its ability to increase expression of a reporter gene in both the presence and absence of ligand treatment. *Id.* at 3. This meets the limitations of the indicated claims, because the method taught by WO 9621677 involves transfection of a test gene into a cell, treating a cell with ligand, and isolating the positive clones. *Id.* at 12. WO 9621677 further discloses that the methods can be practiced using the VDR as a heterodimer partner with the RXR receptor. *Id.* at 34. Thus, it would have been obvious to one of skill in the art at the

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time the invention was made to practice the method taught by WO 9621677 involves transfection of a test gene into a cell, treating a cell with ligand, and isolating the positive clones.

Applicant argues that Moore does not disclose the conversion of any ligand precursor into a ligand, and that the test genes of Moore et al. provide the ligands themselves. However, the claims do not make it clear that the test gene comprises a sequence that encodes a protein which is to be tested for activity which converts the inactive ligand into the active form. The method steps only require that the test gene comprise sequences encoding the nuclear receptor, the response element, and the reporter gen. In the instant case, the test genes of Moore et al. are the liver cDNA library, which were to be tested for binding activity. The test genes were converted to active form by the binding of the ligand, and thus were themselves converted to an active form, and activated the nuclear receptor.

### *Conclusion*

No claim is allowed.

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*Advisory Information*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245.

The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
January 8, 2003